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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,601

03/10/2004

Edward I. Wulfman

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SPECKMAN LAW GROUP PLLC  
2014-B East Union  
SEATTLE, WA 98122

EXAMINER

MENDOZA, MICHAEL G

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

12/08/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,601	<b>Applicant(s)</b> WULFMAN, EDWARD I.	
	<b>Examiner</b> MICHAEL MENDOZA	<b>Art Unit</b> 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 5) ☒ Claim(s) 2-17, 19, 21 and 27-35 is/are pending in the application.
- 5a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 2-17, 19, 21 and 27-35 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 2, 3, 5, 21, 27-29, 31, and 35 have been considered but are moot in view of the new ground(s) of rejection. The applicant has amended independent claims 29 to include the new limitation of "and wherein the support layer contacts the overlying layer along the length of the free portion". The new limitation changes the scope of the claim requiring new consideration.
2. Claims 1, 18, 20, and 22-26 have been cancelled.
3. Claims 8, 14, and 29 are currently amended.
4. Claims 2-17, 19, 21, and 27-35 are pending.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-7, 11-13, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al.
7. Conley et al. teaches an intracorporeal medical device comprising: an operating head (40); a catheter comprising a tubular structure, the tubular structure comprising: an overlying layer (28) and a supporting layer (30) defining an internal lumen (37), wherein the support layer comprises a contiguous coil element, a braid element or a weave element including a plurality of loops (92), the support layer being attached to the

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overlying layer at a bonding point and not attached to the overlying layer along a free portion (col. 8, lines 9-14, col. 9, lines 47-53), whereby the support layer is slippable relative to the overlying layer along the free portion when the tubular structure is bent (fig. 8, space 33 between 30 and 28); and a drive shaft (32) extending within, and rotatable and translatable within, the internal lumen (37) of the catheter. It should be noted that Conley et al. does not specifically teach where the support layer contacts the overlying layer along the length of the free portion. However, the device of Conley et al. is fully capable of being configured into the claimed limitation. The device of Conley et al. is flexible. By compressing the top and bottom of the flexible catheter the support layer will contact the overlying layer along the length of the free portion while still allowing air through the sides the flexible catheter (see figure below).

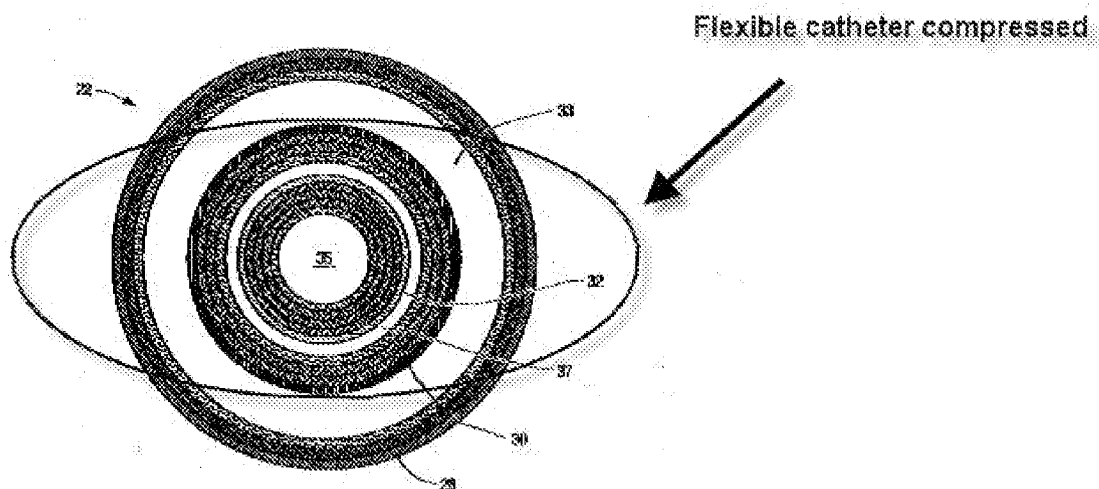


FIG. 8

8. As to claims 2, 3, 5, 21, 27, 28, 31, and 35, Conley et al. teaches the intracorporeal medical device of claim 29, wherein the loops are moveable to reposition relative to each other as the tubular structure is bent (bending would cause movement of the braids); wherein the bonding point is at one end of the support layer (at 34) and the remaining portion of the support layer is the free portion; further comprising a drive system and a control system to direct rotation of the drive shaft (col. 13, lines 1-10); wherein the operating head comprises a cutter (72); wherein the catheter comprises a proximal section having the least flexibility (50), a mid section (52) and a distal section (22) having the most flexibility and the distal section comprises the tubular structure; and wherein the support layer incorporates a less flexible support element (34) at or near the bonding point; wherein the mid section includes a less flexible area that does not incorporate a support layer.

9. As to claim 4 Conley et al. teaches a device that is flexible yet resists crushing. Conley et al. fails to teach about what radius the device can go without kinking. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the flexibility of the device to a desired range before kinking, since it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

10. As to claims 5, 11, and 32-34, Conley et al. teaches the device of claim 29, wherein the overlying layer is formed as a thermally shrinkable sheath (col. 12, lines 24-30), and wherein the sheath encases and contacts the support layer and the support

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layer and sheath are slippable relative to one another along the free portion. It should be noted that Conley et al. fails to teach having a plurality of etches on at least its interior surface. Conley et al. teaches etches that it is known to etch a surface to improve adhesion of layers (col. 11, lines 17-22). Therefore, it would have been obvious to etch the surfaces of the overlying layer to promote the adhesion of the sheath to the overlying layer.

11. As to claims 6, 7, 12, and 13, Conley et al. teaches wherein the sheath comprises a polytetrafluoroethylene material; wherein the sheath comprises PTFE, Teflon<sup>®</sup>, FEP and/or PFA (col. 11, lines 41-47).

12. Claim 30 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Conley et al.

13. Claim 30 is a product-by-process claim. The claimed product appears to be the same or similar to that of the prior art, although produced by a different process. Claim 30 recites welding the support layer of the tubular structure to the operating head. Conley et al. discloses melting the support layer to the operating head. Both processes result in the same product of the support layer being attached to the operating head.

14. In the alternative, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Conley et al. to attach the support layer to the operating head using welding, since welding is a mechanical expedient to melting the support layer to the operating head.

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15. Claims 8-10, 14, 15, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conley et al. as applied to claims 4-19 and 32-35 above, and further in view of Bagaoisan et al. 6270477.

16. As to claims 8, 14, and 19, Conley et al. teaches the device of claim 6. It should be noted the Conley et al. fails to teach a contiguous coil element and the contiguous coil element comprises of a wire and a plurality of gaps between each loop. Conley et al. teaches the use of braided wire to reinforce the support layer.

17. Bagaoisan et al. teaches the use of a braided wire or coil having gaps (col. 7, lines 35-39) to reinforce a tubular body to prevent bucking or undesirable bending of the tubular body (col. 7, lines 13-16). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Conley et al. in view of Bagaoisan et al. to use a coiled wire as opposed to a braided wire, because the coiled wire is a mechanical expedient to a braided wire for reinforcing a tubular body.

18. As to claims 9 and 15, Conley/Bagaoisan teaches a device that is flexible yet highly resistant to kinking. Conley/Bagaoisan fails to teach the length of each gap being 10-200 percent of the width of the wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed gap range limitation, since it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

19. As to claim 16, Conley/Bagaoisan teaches the device of claim 10, wherein the sheath is bonded to the support layer at a bonding point located at one end of the sheath and the sheath is capable of slipping along the support layer as the tubular structure is bent (col. 8, lines 9-14, col. 9, lines 47-53).

20. As to claim 17 Conley/Bagaoisan teaches a device that is flexible yet resists crushing. Conley et al. fails to teach about what radius the device can go without kinking. It would have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the flexibility of the device to a desired range before kinking, since it has been held that where the general condition of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

### ***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of



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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 10:00 a.m. - 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, GARY JACKSON, at (571) 272-4697.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to***

***TC3700\_Workgroup\_D\_Inquiries@uspto.gov.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Mendoza  
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Examiner, Art Unit 3734  
11/23/2011

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